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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,066	05/29/2001	Thomas R. Fuerst	4600-0293.20	7789

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EXAMINER
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WORTMAN, DONNA C 9

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/769,066

Applicant(s)

FUERST ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-14, 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14, 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Applicant's election without traverse of Group I, claims 11-14 and 18, in Paper No. 8 is acknowledged.

Claims 19-24 were canceled in Paper No. 8.

Accordingly, claims 11-14 and 18 are pending and under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 12, and 13 are unclear in reciting "encoding a polypeptide derived from the carboxy-terminal 549 amino acids of HEV reading frame 2" since it is not clear what modifications can be made to the nucleic acid sequence that encodes the carboxy-terminal 549 amino acids of HEV reading frame 2 and still fall within the claim limitations. While the specification at page 7 mentions that the polypeptide may have amino acids deleted from the carboxy terminus of the 549 amino acid polypeptide, e.g., it does not disclose what other modifications (deletions, additions, substitutions) fall within the limitation intended by "derived."

Claim 18 is indefinite because it recites "the expression vector of claim 11" without antecedent in claim 11.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 11-14 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substantially isolated nucleic acid molecule encoding a polypeptide consisting of the carboxy terminal 549 amino acids of HEV open reading frame 2, does not reasonably provide enablement for a substantially isolated nucleic acid molecule encoding a polypeptide derived from the carboxy terminal 549 amino acids of HEV open reading frame 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. While the term "derived" is indefinite as discussed above, given its broadest reasonable interpretation, it encompasses any type of change, including any and all deletions, and/or any and all additions, and/or any and all substitutions in the carboxy terminal 549 amino acids of HEV open reading frame 2. Further, since the claims do not require any particular function for the polypeptide that has been derived from the carboxy terminal 549 amino acids of HEV open reading frame 2, the claims reasonably appear to encompass a virtually infinite number of variations of the claimed nucleic acid sequence. The specification does not provide sufficient guidance for one of skill in the art to make and use an infinite number of nucleic acid sequences without undue experimentation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-14 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,514,690 to Li et al., cited on PTO 892, attached. Li et al. disclose nucleic acid sequences that encode HEV ORF 2 polypeptides derived from the C-terminal 549 amino acids of HEV ORF 2. In particular, Li et al. disclose nucleic acids encoding an HEV ORF 2 polypeptide consisting of amino acids 394-660, as well as nucleic acids encoding portions of the HEV ORF 2 referred to as 2.0, 2.1, and 2.2 (see claim 1, Fig. 5 and Fig. 6, e.g.), which are not seen to be any different from the claimed nucleic acids which are interpreted as reading on any nucleic acid sequence that falls within the nucleic acid sequence that encodes the C-terminal 549 amino acids of HEV ORF 2. US Patent No. 6,514,690 issued from a continuation-in-part of application 08/617927, filed September 24, 1994, which disclosed the subject matter relied upon in this rejection. The instant claims receive the benefit of the filing date of parent application 08/327952, viz. October 24, 1994.

Claims limited to the recitation of a substantially isolated nucleic acid molecule encoding a polypeptide consisting of the carboxy terminal 549 amino acids of HEV open

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reading frame 2, and/or a substantially isolated nucleic acid molecule consisting of SEQ ID NO:3 or SEQ ID NO:4 would be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw  
March 18, 2003